IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES ON ATTACHED EXHIBIT A**	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE TESTIMONY OF MS. ELAINE DUNCAN

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude the opinion testimony of Defendants' regulatory affairs professional witness, Elaine Duncan ("Ms. Duncan"), in its entirety. In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Ms. Duncan has not previously been found qualified to testify as an expert witness. *See* Ex. B, Duncan Dep., October 6, 2015, at 71:5-16 (*Mullins et al. v. Ethicon, Inc., et al.* Case No. 2:12-cv-02952). Ms. Duncan holds a Master's degree in Mechanical Engineering and is the President of Paladin Medical, Inc. Ex. C, Duncan TVT-R Report, at 1; Ex. D, Duncan CV. According to Ms. Duncan's CV: "Paladin Medical, Inc., established in 1987, provides regulatory and clinical consulting, as well as contract technical management to emerging medical product programs. Services include engineering and process analysis, clinical/regulatory affairs consulting, and medical product new-business assessment." Ex. D, Duncan CV. Ms. Duncan states that her task was to "address the developmental history, design control, and risk

management processes" of Ethicon's products, as well as rebutting the work of Plaintiffs' expert witnesses, Dr. Russell Dunn and Ms. Anne Wilson. *See* Ex. C, Duncan TVT-R Report; Ex. E, Duncan TVT-O Report; and Ex. F, Duncan Pelvic Organ Prolapse (POP) Report.

Ms. Duncan stated in her reports that: (1) her company is "dedicated to the service of medical device manufacturers" (*See* Ex. C, Duncan TVT-R Report, at 1); and (2) her "company specializes in new medical technology development and regulatory strategies. *Id.* Throughout the deposition, as detailed below, it was clear that Ms. Duncan's dedication to the service of device manufacturers such as Ethicon has made her nothing more than an apologist for Ethicon's failures. While her personal opinions can be her own, something more is required for her to be able to testify as an expert in these cases. She cannot do so because her opinions are not based on facts related to the product at issue, are nothing more than *ipse dixit* opinions, and lack any reliable foundation or methodology. Most concerning, Ms. Duncan's opinions rest squarely on the FDA's 510(k) clearance of the Ethicon devices and FDA regulations, evidence that this Court has repeatedly held is inadmissible and misleading.

Ms. Duncan's opinions are both contrary to law and present a serious risk of confusing the issues and misleading the jury in this case. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.')(*citing Daubert*, 509 U.S. at 596). As this Court noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, at *42-43 (S.D.W.V. 2013). Here, Ms.

Duncan's testimony runs afoul of this Court's prior rulings and, accordingly, she should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Ms. Duncan to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Ms. Duncan is qualified and her testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014)

reconsideration denied, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, her testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id*.

1. Ms. Duncan's Opinions Must Be Excluded Because They Rely on the FDA 510(k) and Regulatory Processes

Ms. Duncan's opinions must be excluded in their entirety because they rely on FDA requirements, Ethicon's compliance with these requirements, the FDA's intent or state of mind with regard to Ethicon's products and conduct, and certain Ethicon design control standards that she asserts were followed by Ethicon. Even if Ms. Duncan did possess the requisite qualifications, as briefed many times to this Court, such opinions are based on inadmissible evidence and therefore must be excluded. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 578 (S.D. W. Va. 2014).

This Court has repeatedly held that evidence related to the FDA regulatory requirements and its 510(k) process are inadmissible and misleading. In *Lewis v. Johnson & Johnson,* 991 F. Supp. 748, 756 (S.D.W. Va. 2014), this Court unequivocally held that evidence regarding the FDA 510(k) clearance of Ethicon's TVT-R was not admissible: "In sum, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court." In conformity with that oft repeated decision, this Court has also excluded under *Daubert* experts whose opinions rely on or concern the FDA's regulatory activities. For example, in *Winebarger v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 53892, at *54-55 (S.D. W. Va. Apr. 24, 2015), this Court considered why such opinions must be struck, explaining:

> If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement. Such a perception of the product is erroneous, given

> that the product was cleared for market through the FDA's 510(k) process, which "does not in any way denote official approval of the device. 21 C.F.R. §807.97 (2012).

Moreover, in *Sanchez v. Boston Sci. Corp.*, 2014 U.S. Dist. LEXIS 137189, at *95-96 (S.D. W. Va. Sept. 29, 2014), this Court considered a *Daubert* motion to exclude certain opinions by Plaintiff expert Peggy Pence that relied, in part, on FDA regulations. The Court struck those opinions under *Daubert*, explaining:

> Dr. Pence also utilizes FDCA provisions and FDA regulations to craft criteria for the information that should be included in medical device labeling. . . . *Daubert*, however, advises courts to keep in mind the other rules of evidence when evaluating expert testimony. Rule 403, which permits exclusion of relevant evidence "if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury," . . . Fed. R. Evid. 403, carries particular significance in *Daubert* decisions because "[e]xpert evidence can be both powerful and quite misleading." Here, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the failure-to-warn claim than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in California, whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling materials. Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations.

Here, the FDA regulatory process and its clearance of Ethicon's devices through the 510(k) process are inextricably woven throughout the entirety of Ms. Duncan's opinions. In her report, Ms. Duncan repeatedly expressed that Ethicon's products complied with FDA regulations. *See* Ex. C, Duncan TVT-R Report, at 12. Ms. Duncan explained that "the performance of the product is evaluated by way of examination of the application [510(k)] through the appropriate and knowledgeable branch of the FDA. The application contents, and thus the evidence of safety and performance for a surgical mesh, follows the FDA's standard…" *Id.* Ms. Duncan further stated that "Ethicon's TVT 510(k) application follows this guidance." *Id.* Moreover, Ms. Duncan stated that "[t]he FDA considers how well the product performs to

the standards identified within the Guidance…[w]hen satisfied, the FDA issues the 510(k)." *Id.* Ms. Duncan even states that "I have researched the FDA's records and confirmed that Ethicon received a number of 510(k) clearances for the TVT products. These applications follow strict submission content examinations and must meet the FDA's professional, scientific review standards." *Id.* at 13. If Ms. Duncan were allowed to "express to the jury that Ethicon's products complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement." *See Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *54-55.

When questioned at her prior deposition in the *Mullins* case, Ms. Duncan admitted that she could not issue her report or formulate her opinions without referencing and considering the FDA requirements and 510(k) process:

> Q. Can you do what you did in this report without looking at and considering the FDA regulations concerning medical devices?
> A. You have to consider them.
> Q. And you considered the FDA regulations concerning medical devices in your report and in your opinions that you reached in this case; right?
> A. As one of many things that I considered.
> Q. And you're not able to issue this report without considering the FDA regulations. Is that your testimony?
> A. No, I could go back and revise the report and leave out FDA regulations, but it would be less than a diligent job on my part because I have to be present with respect to standards and regulations and best practices that are current in each of these phases. So if you would want me to go back and revise the report, for example, and take out just FDA regulations, it would be peculiar at best.
> Q. Would it be a different report?
> A. I can't say without attempting to do it. It wouldn't be what I normally do as a part of due diligence.

Ex. B, Duncan Dep. October 6, 2015, at 167:15-168:12; *see also id.* at 185:7-10) ("Q. Are you saying that you could not do a comprehensive due diligence without considering the FDA regulations in connection with this report? A. It would be less than professional.").

Ms. Duncan also previously confirmed her reliance on the FDA regulations in the *Mullins* case, testifying that she had to consider the FDA regulations in reaching her conclusions

concerning the appropriateness of Ethicon's conduct with respect to the TVT. Ex. B, Duncan Dep. October 6, 2015, at 183:22-184:4. Ms. Duncan now seems to claim that she may be able to render her opinions without referencing the 510(k) process. *See* Ex. G, Duncan Dep. March 31, 2016, at 102:23-103:12. However, Ms. Duncan also now takes the position that she has taken into account "any regulatory approval in any country" in arriving at her opinions in this case. *Id*., at 118:13-22. She cannot have it both ways and her prior testimony along with her "taking regulatory approval" into account is really nothing more than her parroting the 510(k) process.

Ms. Duncan's reports in this case use the term 510(k) seventeen (17) separate times in her TVT-R report, fifteen (15) separate times in her TVT-O report, and seven (7) times in her report coving various prolapse products. *See* Ex. C, Duncan TVT-R Report; Ex. E, Duncan TVT-O Report; Ex. F, Duncan POP Report. Moreover, Ms. Duncan repeatedly opines that "Ethicon received a number of 510(k) clearances" and that "[t]hese applications follow strict submission content examinations and must meet the FDA's professional, scientific review standards"—a preview of what she would like to tell the jury. *See* Ex. C, Duncan TVT-R Report, at 13.

In short, Ms. Duncan's opinions are so intertwined with inadmissible evidence concerning the FDA regulations and the 510(k) process that they must be excluded from this trial under *Daubert*.

2. Ms. Duncan's Methodology is Unreliable Because it is not the same Methodology that she Employs in her Field

Ms. Duncan has testified that in order to do her job, she has to consider FDA regulations. Ex. B, Duncan Dep. October 6, 2015, at 162:24-163:2 (*Mullins et al.* Case No. 2:12-cv-02952); Ex. G, Duncan Dep. March 31, 2016, at 103: 5-12. Ms. Duncan has also testified that issuing a report without considering FDA regulations "wouldn't be what I normally do as a part of due diligence." Ex. B, Duncan Dep. October 6, 2015, at 167:23-168:12 (*Mullins et al.* Case No.

2:12-cv-02952). Therefore, if Ms. Duncan somehow now intends to testify without referencing the FDA or 510(k) clearance of Ethicon's devices, this would be outside of Ms. Duncan's professional expertise. Ms. Duncan states that her assignment in this matter was to "address the developmental history, design control and risk management . . . associated with the design, manufacture and ***continuous regulatory oversight***" of Ethicon's products. Ex. C, Duncan TVT-R Report, at 1 (emphasis added). Ms. Duncan also frames her reports at the outset by stating that her opinions are based upon her expertise with medical device "regulation." *Id*. That is likely because Ms. Duncan is a Regulatory Affairs Professional. Ex. D, Duncan CV. Ms. Duncan even claimed at her deposition that she couldn't answer a question ***because*** she is "a regulatory person." Ex. G, Duncan Dep. March 31, 2016, at 71:6-13. Therefore, if Ms. Duncan were to testify without reference to the FDA or 510(k), it would require a different set of skills than she uses in her profession, where she files and supports 510(k)s and provides regulatory consulting to medical device companies. *See* Ex. C, Duncan TVT-R Report, at 1-4; Ex. D, Duncan CV.

This is precisely the type of unreliable methodology and testimony that *Daubert* and its progeny are aimed at preventing. "The Supreme Court has said that '[t]he objective of [the *Daubert* gatekeeping] requirement…is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Mathison v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 59047, at *33 (S.D. W. Va. May 6, 2015 (quoting *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). As this Court has made clear, when the "deposition testimony plainly reveals that [the designated expert] employed less intellectual rigor in forming this opinion as an expert witness than [s]he employs in h[er] field," that expert's testimony is inadmissible and should be excluded." *Id.*

3. Ms. Duncan's Opinions are Unreliable Because they Lack Sufficient Foundation and are Outside her Field of Expertise

Ms. Duncan's opinions regarding the TVT-R and TVT-O risk assessment lack sufficient foundation. Ms. Duncan's confusing endorsement of Ethicon's "Legacy" risk assessment—in which Ethicon assessed the risk of the TVT-R and TVT-O devices together—is unreliable because she lacks the requisite foundation of knowledge and qualifications. Ms. Duncan suggests that the TVT-R and TVT-O devices can properly be combined in one risk assessment. *See* Ex. C, Duncan TVT-R Report, at 41-42. However, Ms. Duncan clearly stated that the differences in the risk profiles between these two products are outside her field of expertise:

> Q. If Ethicon's experts, urogynecological and gynecological and neurology experts, the medical experts, have testified that this paper does, indeed, indicate that there are different risk profiles for the Retropubic and the transobturator midurethral slings, you would have no reason to disagree with those expert opinions; would you?
> ***
> A. This is outside my field of expertise.

Ex. G, Duncan Dep. March 31, 2016, at 172:13-20.

Equally as troubling, Ms. Duncan demonstrated at her deposition that she does not understand the differences between the TVT-R and TVT-O procedures. When asked if she understands that the TVT-R and TVT-O are implanted into different locations in a woman's pelvis, Ms. Duncan could only reply, "It was my understanding that the mesh material, essentially, winds up, more or less, in the same location." Ex. G, Duncan Dep. March 31, 2016, at 124:17-19. Ms. Duncan's understanding of the differences between the TVT-R and TVT-O is incorrect and the two devices are inserted into different locations through different insertion techniques.[1] Ms. Duncan acknowledged at her deposition that her understanding of these two

[1] *See* Araco, F. *TVT-O vs. TVT: A Randomized Trial in Patients with Different Degrees of Urinary Stress Incontinence*. Int. Urogynecol. J. 19:917-926 (2008) (noting that the TVT-R is "placed anterior to the

devices factored into the opinions she gave in this case. Ex. G, Duncan Dep. March 31, 2016, at 124:20-24. Ms. Duncan's opinions about the "Legacy" risk assessment of these two devices is not based the witness's knowledge or understanding of the evidence—because she does not have an accurate knowledge or understanding of the differences between the two devices she is opining about. As such, Ms. Duncan's opinions about the TVT-O and TVT-R risk assessment are unreliable because they rest on an unreliable foundation. *See* Fed. R. Evid. 702. Moreover, her incorrect, inconsistent and confusing understanding of these products would greatly confuse and distract the jury. At bottom, there is no real value in having someone get up in front of the jury, who literally has no understanding of the device or how it is used, to offer an opinion that the product and its design are appropriate. Ms. Duncan offers nothing even remotely scientifically reliable to aid the jury's determination of the issues in this case, and should not be allowed to act as Ethicon's hand-selected apologist.

4. Ms. Duncan's Opinions Must be Excluded Because they Rely on Clinical Conclusions She is Not Qualified to Give

Ms. Duncan's opinions must also be excluded because they rely on clinical conclusions that she is not qualified to give. Specifically, in her report, Ms. Duncan opines that "it is important to observe that polypropylene mesh midurethral slings ("MUS") (*i.e.*, TVT), have become the 'gold standard' or 'standard of care' for patients who require surgical treatment of SUI." *See* Ex. C, Duncan TVT-R Report, at 11. Ms. Duncan also opined that "[a]s the AUGS pointed out '…there is now adequate evidence that the MUS is associated with less pain, shorter hospitalization, faster return to usual activities, and reduced costs as compared to historic

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urethra through a minimal vaginal incision" and the TVT-O device is "inserted from the suburethral space into a strictly perineal region limited medially and superbly by the levator ani muscle, inferiorly by the perineal membrane and laterally by the obturator internus muscle. The tape then perforated the obturator membrane and muscles and exited through the skin after traversing adductor muscles and subcutanoues tissue.").

operations that have been used to treat SUI over the past century.'" Ex. C, Duncan TVT-R Report, at 11. Ms. Duncan has testified that "It's my conclusion that this device, based on the clinical experience and the robust endorsement of this device by the AUGS organization, and even the FDA, that I would be foolhardy to try to suggest there's a better way to make this product." Ex. B, Duncan Dep. October 6, 2015, at 23:8-12 (*Mullins et al.* Case No. 2:12-cv-02952). Ms. Duncan's opinion here is essentially that she believes the TVT product is clinically safe and effective, and, therefore, it must have been designed according to appropriate industry standards. This opinion must fail because Ms. Duncan is not qualified to offer any opinions on the safety and efficacy of Ethicon's SUI and POP devices. Again, she just cherry-picks a document that is outside her field of expertise, and if it supports Ethicon, she says it is evidence that Ethicon must be right. That requires no expertise, and the jury is more than capable of reading those same documents, or would benefit more by hearing from someone who is actually qualified to talk about them.

Ms. Duncan is not a medical doctor; she has never conducted a clinical trial, has never treated a woman with SUI, and is not a member of AUGS. Ex. B, Duncan Dep. October 6, 2015, at 24:8-19 (*Mullins et al.* Case No. 2:12-cv-02952). Ms. Duncan doesn't have any "anatomical or special medical training in the TVT device and its use in woman." *Id.*, at 24:20-23 (*Mullins et al.* Case No. 2:12-cv-02952). Most significantly, Ms. Duncan admitted that she was not qualified to give expert opinions on the medical or clinical risks and benefits of the TVT device:

> Q. And because you're not a medical doctor, you're not able to give expert opinions on the medical/clinical risk-benefit of the TVT-R mechanical cut to patients; are you?
> A. Ma'am, I can read and discern the documentation, ***but I wouldn't give an expert opinion about it.***

Ex. B, Duncan Dep. October 6, 2015, at 112:22-113:4 (emphasis added) (*Mullins et al.* Case No. 2:12-cv-02952).

Despite this, Ms. Duncan's opinions concerning the appropriateness of the design of Ethicon's SUI and POP products rest of the very medical and clinical opinion that she is not qualified to give: that midurethral slings are the "standard of care." *See* Ex. C, Duncan TVT-R Report, at 11. It is not appropriate methodology for an expert like Ms. Duncan to choose one opinion piece by one organization and utilize that as the foundation for her opinions. Because Ms. Duncan is not qualified to give the foundational opinion, her opinions about the appropriateness of the design of Ethicon's SUI and POP devices must be excluded. Accordingly, Plaintiffs respectfully request that this Court exclude the opinions of Ms. Duncan as lacking proper foundation and expertise.

5. Ms. Duncan's Opinions Must be Excluded Because she Improperly Relies on the AUGS Position Statement on Midurethral Slings in her POP Report

Ms. Duncan's opinions must also be excluded because they are based on unreliably extrapolating clinical data regarding SUI devices and attempting to apply it to POP devices. In each of her three reports in this case, Ms. Duncan relies upon the 2014 AUGS Position Statement on Mesh Midurethral Slings and she repeats the same statement in each report: "Further, it is important to observe that polypropylene mesh midurethral slings ("MUS") (*i.e.*, TVT), have become the "gold standard" or "standard of care" for patients who require surgical treatment of SUI." Ex. C, Duncan TVT-R Report, at 11; Ex. E, TVT-O Report, at 11; Ex. F, POP Report, at 12. This statement made by the American Urogynecologic Society (AUGS) relates to a category of products to treat SUI—and not POP. Whether or not midurethral slings are considered the "standard of care" for the treatment of SUI is immaterial to Ms. Duncan's assessment of the design of Ethicon's POP products, which are designed to treat an entirely different condition.

The effectiveness of Ethicon's SUI devices in comparison to other SUI treatments simply has no bearing on the design of Ethicon's POP products. Ms. Duncan's attempt to extrapolate information about medical and clinical risks from an SUI device to various devices for the treatment of POP is improper, unreliable, and would waste time and distract the jury. Accordingly, Plaintiffs respectfully request that this Court exclude the opinions of Ms. Duncan as being unreliable and irrelevant.

6. Ms. Duncan's Rebuttal Opinions of Dr. Russell Dunn are Outside of her Area of Professional Expertise

In addition to addressing the "continuous regulatory oversight" of Ethicon's products, Ms. Duncan also was tasked with rebutting the opinions of Plaintiffs' expert witness, Dr. Russell Dunn. *See* Ex. C, Duncan TVT-R Report, Ex. F, Duncan POP Report. Dr. Dunn is a chemical engineer and polymer scientist who opinions on how the chemical properties of polypropylene subject it to oxidative degradation. *See* Ex. H, Dunn Report. Ms. Duncan's rebuttal of Dr. Dunn's opinions rests on a foundation of chemical engineering and polymer science which she simply does not possess. *See* Ex. F, Duncan POP Report, at 23-25. Ms. Duncan has testified that she is neither a professional engineer nor a polymer scientist:

> Q. And do you hold yourself out as an expert in biomedical engineering?
> A. I do not consider myself a professional engineer in the context of the PE, professional engineering license.
> Q. And you're not a polymer scientist; are you?
> A. No, ma'am.

Ex. B, Duncan Dep. October 6, 2015, at 112:12-18 (*Mullins et al.* Case No. 2:12-cv-02952). Moreover, Ms. Duncan's rebuttal of Dr. Dunn stretches to clinical and engineering topics which are also outside her area of expertise. For instance, Ms. Duncan notes that "[c]learly, reduction in mesh strength in a normal biologic environment after tissue healing occurs is not viewed as a defect; it can be viewed as a design attribute." Ex. F, Duncan POP Report at 25. Ms. Duncan

has consistently held the position that she does not have expertise in the biomechanics of the pelvic floor environment:

> Q. And it's your understanding that if the mesh is stiff after ingrowth, it is not a concern, right?
> A. I would say I don't know how to answer your question. They attempted to design Prolift M as an alternative, and I do not have knowledge to tell you from a biomaterials point of view if that was successful. ***It's not my expertise***.

Ex. G, Duncan Dep. March 31, 2016, at 43:2-8 (emphasis added); *id*. at 38:20-24 ("Q. You would agree with me that the vaginal space is a dynamic space that is not static; in fact, it expands and contracts? A. Sir, I can't agree with you. I don't have expertise in that area."). Ms. Duncan's rebuttal opinions of Dr. Dunn are simply outside of her area of professional expertise and as such should be excluded.

7. Ms. Duncan Applied No Discernible Methodology to Arrive at her Opinions

Ms. Duncan states that her assignment was to "address the developmental history, design control and risk management processes" associated with Ethicon's SUI and POP devices. Ex. C, TVT-R Report at 1; Ex. E, TVT-O Report at 1; Ex. F, POP Report at 1. What Ms. Duncan did to "address" these processes is unclear. Ms. Duncan repeats the same crafted statement for several of the products: "Ethicon's design history file and CE Mark files for [product name] are very thorough and demonstrate compliance with the FDA's QSRs as well as European Directive Standards." Ex. F, Duncan POP Report, at 13-14. In addition to the FDA issues Ms. Duncan's statements like these raise (discussed above), she has not been able to point to any sound methodology that she employed in arriving at these opinions. In fact, when asked to explain the methodology for arriving at these opinions, Ms. Duncan could only reply, "I reviewed the documents I was given, yes, sir." Ex. G, Duncan Dep. March 31, 2016, at 27:15-16. When asked whether she reviewed the "entire design history file," Ms. Duncan could only reply "… To

the extent I was given the documents…." Ex. G, Duncan Dep. March 31, 2016, at 27:17-20. Her report otherwise contains no methodology for how the determined that Ethicon's design history files "are very thorough and demonstrates compliance with the FDA's QSRs…" *See* Ex. F, Duncan POP Report, at 13-14. Ms. Duncan's broad and vague statements serve as her rubber stamp of approval for the company that hired her in this matter. She simply sites to broad ranges of Ethicon documents and then declares that these files are "very thorough and demonstrate compliance with the FDA's QSRs as well as the European Directive Standards." Ex. F, Duncan POP Report, at 13-14. These broad statements do not show that Ms. Duncan's analysis is based on a reliable methodology "reliably applied…to the facts of the case." Fed. R. Evid. 702. This is nothing more than "it is because I say it is" *ipse dixit* testimony that is not helpful to the jury and has previously been rejected by this Court. *See* Tyree 54 F. Supp. 3d at 583-585. Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude—as it should here—that there is too large of an analytical gap between the data and the opinions proffered. *See Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997).

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Ms. Duncan is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in Ms. Duncan's opinions, Ethicon cannot carry this burden and her testimony should be excluded.

Dated: April 21, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Edward A. Wallace
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